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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,359	04/20/2004	Tom Westberg	F-5495 DIV (9360-0172.01)	4891
69275	7590	09/11/2009	EXAMINER	
COOK ALEX LTD. 200 WEST ADAMS STREET SUITE 2850 CHICAGO, IL 60606			WIEST, PHILIP R	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/828,359	<b>Applicant(s)</b> WESTBERG ET AL.	
	<b>Examiner</b> Philip R. Wiest	<b>Art Unit</b> 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 5/22/09.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Amendment***

In the reply filed 5/22/09, applicant amended claims 1, 7, and 13. Claims 1-18 are currently pending.

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 2, 4, 5, 7, 10, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamen et al. (5,350,357) in view of Lundback (US 4,648,877).

Kamen et al. (hereafter Kamen) discloses a medical fluid pumping device comprising a plurality of pumping stations (P1, P2), both of which comprising an inlet and an outlet, that operate by applying positive and negative pressures to a membrane. A controller applies pressure to the pumping stations in tandem, such that they synchronized to be alternately filled and emptied (Column 19-Lines 49-51). Specifically, the controller switches between a first flow mode, in which the pump strokes draw fluid for a first duration into the fluid inlet of the first pump and expel fluid for a second duration from the fluid outlet of the second pump, and vice versa in a second flow mode. By operating in tandem, the pumps are capable of continuously receiving fluid and pumping it from a source to a destination. Regarding Claims 4, 5, 10, 11, 16, and 17, pneumatic fluid

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pressures are applied to the pumps and valves (Column 3, Lines 15-20). The controller operates the pumps in tandem such that the first pump is in a draw stroke while the second pump is in a pump stroke, and vice versa. By using this type of alternating, tandem pumping method, it is ensured that a constant stream of fluid is being pumped into the inlet of the system, thereby improving the speed at which the device operates (Column 31, Line 58 through Column 33, Line 6). Kamen, however, does not specifically teach that the pumping system operates such that the first duration is longer than the second duration, thereby creating continuous fluid input and pulsatile fluid output.

Lundback discloses a pumping system and method that uses a pneumatic driving means to provide a pulsatile outflow and a continuous inflow. The method disclosed by Lundback includes a pumping stroke and a return stroke that operate in succession to one another in order to create a continuous inflow and a pulsatile outflow (see columns 6-7). The first duration (fill phase) allows the system to be gradually filled with fluid, and the second duration (expulsion phase) rapidly ejects the fluid from the chamber, thereby creating pulsatile outflow. This type of pump may be used in a variety of types of fluid systems, including extracorporeal blood pumping systems, in order to provide improved control over the flow rate of the fluid being pumped based on the pressure of the fluid source. Pumps having continuous inflow and pulsatile outflow are known in the art as having a number of advantages over traditional pumping means, such as the ability to self-regulate the rate at which fluid is passed through the pump (Column 2, Lines 55-61). Additionally, blood pumps of this type are well known in the art because they allow for

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fluid to be continuously received through the inlet, while producing a pulsatile outflow that resembles normal physiological flow (see Abstract). Finally, because Lundback's pumps are self regulating, it becomes possible to use a pair of them in tandem, driven in parallel or separately (Column 4, Lines 44-51). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the blood processing system of Kamen with the pumping method of Lundback in order to provide a continuous inflow and pulsatile outflow, thereby providing a pressure-sensitive pumping system that mimics physiological blood flow.

3. Claims 2, 3, 6, 8, 9, and 12-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamen in view of Lundback, and further in view of Pages et al. (US 5,954,971). Kamen and Lundback reasonably suggest the device substantially as claimed, but do not specifically teach that the pumping system is used in conjunction with a blood processing apparatus for removing leukocytes. Pages et al. (hereafter Pages) discloses a blood processing system for removing leukocytes from blood comprising a plurality of blood inlets having flow control means (115v and 120v), a leukocyte filter 140, and a pump station 132, and a plurality of blood collection containers (145, 150) that receive blood from a separation device. The filter 140 communicates with blood collection containers (145, 150) that is located downstream of the filter. Although Pages teaches that a peristaltic pump is used to convey fluid through the system, any type of known medical pump may be used. Fluid-actuated

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pumps such as Kamen are well known in the medical art because they allow for continuous, precisely-controlled fluid flow. Therefore, it would have been obvious to use the fluid-actuated pumping system of Kamen to convey fluid through the blood processing system of Pages, in order to provide an alternate, more efficient means for filtering blood.

### ***Response to Arguments***

Applicant's arguments filed 7/31/09 have been fully considered but they are not persuasive. Applicant argues that the combination of Kamen and Lundback does not reasonably suggest the claimed device.

First, it is important to note that applicant's claim language ("the fluid pressure actuator including a control function to switch between a first flow mode, ..., and a second flow mode...") is **functional language**. Kamen and Lundback need only teach or suggest a device that is capable of performing the claimed function. In order to overcome this, applicant is advised to change the independent claims to state "... the fluid pressure actuator *programmed to switch*...".

Applicant also argues that it would not have been obvious to modify Kamen with Lundback because the two systems operate in different manners, specifically that Lundback's pump chambers may not be used with Kamen's cartridge system. However, the test for obviousness is not whether the features of a secondary reference

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may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references.

Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In this case, Lundback clearly defines the advantages of providing a pulsatile outflow, and one of ordinary skill in the art would have been motivated to provide a pulsatile outflow in an existing medical fluid transfer system. Obvious to modify Kamen's pump stations to provide pulsatile outflow in order to create an outflow pattern that mimics physiological flow.

Additionally, regarding applicant's argument that Lundback's device does not have an ejection phase (second duration) that is shorter than the fill phase (first duration), Lundback clearly teaches that the pump station receives a constant stream of fluid in a first phase, and ejects it in a pulsatile manner (i.e. more quickly) in a second phase.

Finally, applicant argues that that Lundback does not teach or suggest two pump stations operating in tandem. This argument has not been found persuasive.

First, Kamen clearly teaches a system wherein two pump stations are operated in tandem such that one station may fill while the other drains. The Lundback reference was used to teach that these pump stations may be configured to have a pulsatile outflow, not that they may be arranged in tandem. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of

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references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Regardless, Lundback also teaches that a plurality of pump chambers may be disposed in a system, either in parallel or separately (see Column 4, Lines 44-51).

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571)272-3235. The examiner can normally be reached on 8:30am-5pm EST.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phil Wiest/  
Examiner, Art Unit 3761

/Leslie R. Deak/  
Primary Examiner, Art Unit 3761  
9 September 2009